Shaughnessy Number: 128857

Date out of EAB: SEP 27 1988

To: Lois Rossi/Larry Schnaubelt
Product Manager 21
Registration Division (TS 767C)

From: Emil Regelman, Supervisory Chemist
Environmental Fate Review Section #2
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (TS 769C)

Thru: Paul F. Schuda, Chief
Environmental Fate and Ground Water Branch/EFED (TS 769C)

Attached, please find the EAB review of...

Reg./File #: 707-ERN, -ERR, -ERE, -EER, -ROG, -ERG

Chemical Name: Myclobutanil

Type Product: Fungicide

Company Name: Rohm and Haas

Purpose: response to EFGWB comments on terrestrial field dissipation on parent and 1,2,4-triazole metabolite

Date Received: 9/13/88

Action Code: 111,111,111,111,126,126

Date Completed: _____

EAB #(s): 81017,-18,-19,-20,-21,-22

Monitoring Study Requested: _____

Total Reviewing Time: 2.0 days

Monitoring Study Volunteered: _____

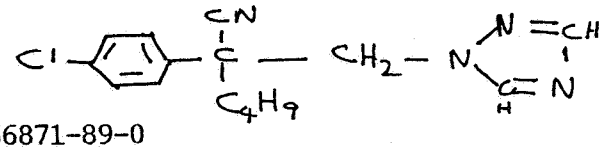
Deferrals to: ___ Ecological Effects Branch

x Dietary Exposure Branch

x Toxicology Branch

1. CHEMICAL:

chemical name: [α-butyl-α(4-chlorophenyl)-1H-1,2-triazole-1-propanenitrile
common name: Myclobutanil
trade name: Systhane, Rally
structure:



CAS #: 66871-89-0
Shaughnessy #: 128857

2. TEST MATERIAL:

3. STUDY/ACTION TYPE: response to EFGWB comments

4. STUDY IDENTIFICATION: n.a.

5. REVIEWED BY:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E. B. Conerly 9/23/88

SEP 27 1988

6. APPROVED BY:

Typed Name: Emil Regelman
Title: Supervisory Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

SEP 27 1988

7. CONCLUSIONS:

The studies discussed in this review are not acceptable.

8. RECOMMENDATIONS:

EFGWB recommends that the applicant agree to perform a field dissipation study on myclobutanil as a condition of registration, after submitting and obtaining approval for the protocol. This should include pre- and post-application day-zero samples, multiple core samples at each time period, and shorter intervals between samples. At least three sites should be used, including one without a cover crop. Application should be at the maximum label rate, or, at the applicant's option, a 2 or 3x rate. EFGWB reserves any further data requirement on triazole at this time. EFGWB defers the following matters on myclobutanil and its triazole metabolite:

to the Residue and Toxicology Branches for an assessment of the dietary risk potential
to the ground water team for a ground water assessment

9. BACKGROUND:

The status of data requirements is as follows:

hydrolysis -- satisfied -- stable at pHs 5, 7, 9
photolysis in water -- satisfied -- stable to photolysis in water
photolysis in soil -- satisfied -- extrapolated $t_{\frac{1}{2}}$ ca. 143 days
aerobic soil metabolism -- satisfied -- $t_{\frac{1}{2}}$ 61-71 days -- major product is 1,2,4-triazole up to ca 15%, with CO_2 and unextractables in lesser amounts
anaerobic soil metabolism -- satisfied -- resistant to anaerobic metabolism -- no detectable degradation after ca. 60 days
leaching - satisfied for parent -- moderately mobile -- k_{ad}s 1.46 - 9.77 for adsorption, 0.47-4.18 for desorption in five soils: clay loam, sand, silt loam, sandy loam, clay -- additional data required re "aged" compound (degradates must be identified and quantified).
terrestrial field dissipation -- discussed below
fish bioaccumulation -- waived, based on low k_{ow}s for parent and degradates. The compound is not expected to bioaccumulate.

These data indicate the following:

1) A major route of disappearance of myclobutanil will be diffusion/dilution since it appears to be resistant to most environmental breakdown processes.
2) A ground water evaluation may be necessary, based on toxicology and residue concerns, since the compound is stable and somewhat mobile.

The terrestrial field dissipation study was previously deemed unacceptable, due to inadequacy of sampling; to lack of immediate post-treatment sampling of the PA site (which means that application rate was not confirmed); a difference of almost an order of magnitude in soil concentration between the two sites, in what should have been comparable samples; and apparent difficulties with the analytical method. The applicant has provided additional discussion relative to these deficiencies:

Studies on the parent:

Rohm and Haas:

1) Zero-day samples are unnecessary since the data are not used quantitatively, and no conclusions would be changed were these data available.
2) ... Since the material is foliarly applied, any material which reaches the soil does so by accident....
3) one should not expect to obtain the same result under ... varied conditions. Rather, the observations should be used to demonstrate the range of initial levels, and the focus should be on the rate of decline.
4) [Rohm and Haas] ... analyzed for free 1,2,4-triazole as well as for parent compound... Triazole was the only

metabolite noted ... at a sufficient level to warrant analysis in the field study. ... the carboxylate metabolite... is a low level, transient material.

EFGWB response [item numbers corresponding to above]:

1) Zero-day samples are used to demonstrate that the specific application under discussion was uniform and at the correct rate. Without this information the other analytical results cannot be adequately assessed.
2) Myclobutanil can reach the soil by means other than incidental contact when foliar application is made. Since the compound is long-lived, a substantial amount could reach the soil through leaf litter and other material from treated crops. However, this type of residue is not presently an issue.
3) We agree that this type of study should be used to demonstrate the range of initial levels and rate of decline of the parent compound. We do not believe that this particular study accomplished that purpose. The apparent difference in rates of decline between these two sites is greater than an order of magnitude. We do not believe that from these data a statement can be made about a probable range of soil concentrations or typical rate of dissipation.
4) We agree with the applicant's position on this issue.

On reexamination of the study report, it appears that the results and conclusions were based on a single core sample at each time period. If this is true, the study is unacceptable. A single core sample is not sufficient, and the analytical results derived from it cannot be used with confidence to draw any conclusions.

A previous review (EBC 5/19/87) also noted that at the first post-application sampling in PA (day 24), ca 80% of the parent had dissipated. While EFGWB agrees that this tends to demonstrate that parent compound would not accumulate in the soil, data from intermediate times would be useful for confirmation.

At the MS site, the apparent soil $t_{\frac{1}{2}}$ was ca 5.5 months (160 days), more than an order of magnitude greater than that in PA.

Studies on Triazole

Because the results are so variable, the Agency has questioned the validity of the analyses on various samples from this study. The applicant defends these results as follows [EFGWB paraphrase]:

Rohm and Haas:

1) Naturally occurring background levels, experimental levels, and detection limits of the method are all of

the same order of magnitude.

2) Sample values were corrected by subtracting corresponding control values.
3) Since these values were of the same magnitude, apparent variability was increased when this "correction" was applied.
4) The values reported were toxicologically insignificant.

EFGWB response :

We have reexamined the original triazole study. It appears that the results and the conclusions are based on one core sample per sampling period. This is unacceptable, since the variability of the application and sampling procedures cannot be assessed without duplicate sampling. The reported values do indicate generally low concentrations of triazine, but there are several samples which are much higher than background. It is doubtful whether a new, similar study would yield much additional information to clarify the situation. If toxicological and residue evaluations indicate a need for the information, a bare-ground exaggerated-rate study would probably be more useful.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: n.a.

11. COMPLETION OF ONE-LINER: attached

12. CBI APPENDIX: n.a.

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information — Does Not Contain National Security Information (E.O. 12065) 9/14/88

1. CHEMICAL NAME: [illegible] (RALLY® NOVA®) 48419 Hed

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
707-ERN	111	40788001	5. RECORD NUMBER 231093-098
707-ERP	111		6. REFERENCE NUMBER 1
707-ERR	111		7. DATE RECEIVED (EPA) 8/16/88
707-ERR	111		8. STATUTORY DUE DATE
707-ERG	134		9. PRODUCT MANAGER (PM) Boes1/Schnaubelt
707-ERO	136		10. PM TEAM NUMBER 21

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

AH

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS 9-13-88

12. PRIORITY NUMBER 29

13. PROJECTED RETURN DATE 10/14/88

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☐ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD

D. ☐ TSS/RD

E. ☐ Other

F. INSTRUCTIONS

Review applicant's response to GDS dated April 12, 1988.

ATTN: Brinson Conerly

16. RELATED ACTIONS

17. 3(c)(1)(D)
- ☐ Use Any or All Available Information
- ☐ Use Only Attached Data
- ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO
- ☐ TB
- ☐ EEB
- ☐ EF
- ☐ PL
- ☐ RCB
- ☐ EFB
- ☐ CH
- ☐ BFSD

19.	To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY								
		ECOLOGICAL EFFECTS								
		RESIDUE CHEMISTRY								
		ENVIRONMENTAL DATE	6							
RD/TSS		CHEMISTRY								
		EFFICACY								
		PRECAUTIONARY LABELING								
BFSD		ECONOMIC ANALYSIS								

20.	21.	22.	23.	24.
☐ Label Submitted with Application Attached	☐ Confidential Statement of Formula	☐ Representative Labels Showing Accepted Uses Attached	Date Returned to RD (to be completed by HED)	Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

EPA Form 8570-12 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE

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INDEPENDENCE MALL WEST PHILADELPHIA, PA. 19105, U.S.A. TELEPHONE (215) 592-3000
CABLE ADDRESS: ROHMHAAS TELEX 845-247 TWX 710-670-5335 TELECOPIER (215) 592-3377

ROHM AND HAAS COMPANY

August 15, 1988

Ms. Lois A. Rossi (PM-21)
Registration Division (TS-767C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Rossi:

SUBJECT: RALLY^{R} Fungicide
EPA File Symbols 707-EER, -ERE, -ERL, -ERN, -ERR, -ROG
Response to EAB Review of April 12, 1988

On June 1, 1988 we submitted a partial response to the subject EAB review, which addressed the deficiencies cited for photodegradation in water (161-2) and mobility (163-1). At the time, we informed you of our intent to address the deficiencies for the terrestrial field dissipation studies (164-1) after we had an opportunity to meet with EAB and clarify the technical issues. That meeting was held on June 16.

Enclosed is a document (3 copies) entitled,

40788001 Morelli, M.A. (1988). Response to EAB Review of April 12, 1988 for RALLY^{R} Fungicide. Rohm and Haas Co. Project ID MAM 88-70.

which incorporates the essential content of the discussion with EAB. Please bring this to the attention of the EAB reviewer, Ms. Conerly. At the request of E. Regelman, EAB Supervisory Chemist, who was unable to attend the meeting, we ask you to provide a copy of this document for his review, as well.

We would appreciate an expedited review so that final EPA approval of our Section 3 applications may proceed in a timely manner.

Sincerely,

Michael A. Morelli

Michael A. Morelli, Ph.D.
Product Registration Manager
Agricultural Chemicals Registration
and Regulatory Affairs

MAM/paw
Enclosures